

## **Summary of Studies Supporting USDA Product Licensure**

| Establishment Name  | Zoetis Inc.  |
|---|--|
| USDA Vet Biologics<br>Establishment Number                                      | 190  |
| Product Code  | 7430.00  |
| True Name   | Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D-Mannheimia Haemolytica Bacterin-Toxoid |
| Tradename(s) / Distributor or<br>Subsidiary<br>(if different from manufacturer) | One Shot Ultra 7 - No distributor specified One Shot Ultra 7 - Zoetis South Africa Ltd                       |
| Date of Compilation<br>Summary  | May 21, 2021   |

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

190 7430.00 Page 1 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Clostridium chauvoei  |
| Study Purpose                 | Demonstrate effectiveness against Clostridium chauvoei  |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | February 3, 1999  |

190 7430.00 Page 2 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Clostridium novyi   |
| Study Purpose                 | Demonstrate effectiveness against Clostridium novyi   |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| USDA Approval Date            | February 3, 1999  |

190 7430.00 Page 3 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Clostridium perfringens Type C  |
| Study Purpose                 | Demonstrate effectiveness against Clostridium perfringens Type  |
|                               | C   |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| USDA Approval Date            | February 3, 1999  |

190 7430.00 Page 4 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Clostridium perfringens Type D  |
| Study Purpose                 | Demonstrate effectiveness against Clostridium perfringens Type  |
| -                             | D   |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| USDA Approval Date            | February 3, 1999  |

190 7430.00 Page 5 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Clostridium septicum  |
| Study Purpose                 | Demonstrate effectiveness against Clostridium septicum  |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| Challenge Description         |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| USDA Approval Date            | February 3, 1999  |

190 7430.00 Page 6 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Clostridium sordelli  |
| Study Purpose                 | Demonstrate effectiveness against Clostridium sordelli  |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | February 3, 1999  |

190 7430.00 Page 7 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Mannheimia haemolytica  |
| Study Purpose                 | Demonstrates effectiveness against Mannheimia haemolytica   |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | June 21, 1991   |

190 7430.00 Page 8 of 12

| Study Type                    | Efficacy  |
|-------------------------------|---|
| Pertaining to                 | Mannheimia haemolytica  |
| <b>Study Purpose</b>          | Demonstrate effectiveness against Mannheimia haemolytica  |
| <b>Product Administration</b> |   |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | August 20, 1999   |

190 7430.00 Page 9 of 12

| Study Type                    | Safety  |
|-------------------------------|---|
| Pertaining to                 | ALL   |
| Study Purpose                 | Demonstrate safety in cattle under field conditions   |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | September 8, 1999   |

190 7430.00 Page 10 of 12

| Study Type                    | Safety  |
|-------------------------------|---|
| Pertaining to                 | ALL   |
| Study Purpose                 | Demonstrate safety in cattle under field conditions   |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | 09/08/1999  |

190 7430.00 Page 11 of 12

| Study Type                    | Safety  |
|-------------------------------|---|
| Pertaining to                 | ALL   |
| Study Purpose                 | Demonstrate safety in cattle under field conditions   |
| <b>Product Administration</b> | Subcutaneous  |
| Study Animals                 | Bovine  |
| <b>Challenge Description</b>  |   |
| Interval observed after       |   |
| challenge                     |   |
| Results                       | Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date. |
| <b>USDA Approval Date</b>     | 09/08/1999  |

190 7430.00 Page 12 of 12